retail establishments) directed to consignees, distributors, retailers, and members of the public.

[54 FR 4008, Jan. 27, 1989, as amended at 66 FR 17358, Mar. 30, 2001; 69 FR 17291, Apr. 2, 2004]

§ 107.240 Notification requirements.

(a) *Notification of a violative infant formula.* A manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act)) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer:

(1) May not provide the nutrients required by section 412(i) of the act and by regulations promulgated under section 412(i)(2) of the act; or

(2) May be otherwise adulterated or misbranded.

(b) *Method of notification.* The notification made pursuant to §107.240(a) shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), FDA's emergency number, 301–443–1240, shall be used. The manufacturer shall send written confirmation of the notification to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter.

(c) *Reports about an infant formula recall*—(1) *Telephone report.* When a determination is made that an infant formula is to be recalled, the recalling firm shall telephone within 24 hours the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter and shall provide relevant information about the infant formula that is to be recalled.

(2) *Initial written report.* Within 14 days after the recall has begun, the recalling firm shall provide a written report to the appropriate Food and Drug Administration district office. The report shall contain relevant information, including the following cumulative information concerning the infant formula that is being recalled:

(i) Number of consignees notified of the recall, and date and method of notification, including, for a recall pursuant to §107.200 information about the notice provided for retail display and the request for its display.

(ii) Number of consignees responding to the recall communication and quantity of recalled infant formula on hand at the time it was received.

(iii) Quantity of recalled infant formula returned or corrected by each consignee contacted and the quantity of recalled infant formula accounted for.

(iv) Number and results of effectiveness checks that were made.

(v) Estimated timeframes for completion of the recall.

(3) *Status reports.* The recalling firm shall submit to the appropriate Food and Drug Administration district office a written status report on the recall at least every 14 days until the recall is terminated. The status report shall describe the steps taken by the recalling firm to carry out the recall since the last report and the results of these steps.

[54 FR 4008, Jan. 27, 1989, as amended at 61 FR 14479, Apr. 2, 1996; 66 FR 17359, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001; 69 FR 17291, Apr. 2, 2004]

§ 107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter for transmittal to the Center for Food Safety and Applied Nutrition (HFS–605), for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The agency will respond within 15 days of receipt by the Center for Food Safety and Applied Nutrition (HFS–605), of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the agency that the recall has been terminated.